

**§ 425.304 Other program requirements.**

(a) *Beneficiary inducements.* (1) ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Consistent with the provisions of paragraph (a)(1) of this section and subject to compliance with all other applicable laws and regulations, ACO, ACO participants and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and the items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(b) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers will be reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(c) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

(d) *Required reporting of NPIs and TINs.* (1) The ACO must maintain, update, and annually furnish to CMS at the beginning of each performance year and at other such times as specified by CMS the list of each ACO participant's TIN and ACO providers/supplier's NPI that is required to be submitted under § 425.204(c)(5)(i).

(2) The ACO must notify CMS within 30 days of any changes to the list of NPIs and TINs.

**§ 425.306 Participation agreement and exclusivity of ACO participant TINs.**

(a) For purposes of the Shared Savings Program, each ACO participant TIN is required to commit to a participation agreement with CMS.

(b) Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO for

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purposes of Medicare beneficiary assignment. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one Medicare Shared Savings Program ACO.

### § 425.308 Public reporting and transparency.

For purposes of the Shared Savings Program, each ACO must publicly report the following information regarding the ACO in a standardized format as specified by CMS:

- (a) Name and location.
- (b) Primary contact.
- (c) Organizational information including all of the following:

- (1) Identification of ACO participants.

- (2) Identification of participants in joint ventures between ACO professionals and hospitals.

- (3) Identification of the members of its governing body.

- (4) Identification of associated committees and committee leadership.

- (d) Shared savings and losses information, including:

- (1) Amount of any shared savings performance payment received by the ACO or shared losses owed to CMS.

- (2) Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

- (e) *Results of claims based measures.* Quality measures reported using a CMS web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

[76 FR 67973, Nov. 2, 2011, as amended at 77 FR 69372, Nov. 16, 2012; 78 FR 74823, Dec. 10, 2013]

### § 425.310 Marketing requirements.

- (a) *File and use.* Marketing materials and activities, as defined in § 425.20, may be used or conducted five business days following their submission to CMS if—

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- (1) The ACO certifies compliance with all the marketing requirements under this section; and

- (2) CMS does not disapprove the marketing materials or activities.

- (b) *Deemed approval.* (1) Marketing materials and activities are deemed approved after expiration of the initial 5 day review period specified in paragraph (a) of this section.

- (2)(i) CMS may issue written notice of disapproval of marketing materials and activities at any time, including after the expiration of the initial 5 day review period.

- (ii) The ACO, ACO participant, ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities as applicable, must discontinue use of any marketing materials or activities disapproved by CMS.

- (c) *Marketing requirements.* Marketing materials and activities must meet all of the following:

- (1) Use template language developed by CMS, if available.

- (2) Not be used in a discriminatory manner or for discriminatory purposes.

- (3) Comply with § 425.304(a) regarding beneficiary inducements.

- (4) Not be materially inaccurate or misleading.

- (d) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

### § 425.312 Notification to beneficiaries of participation in shared savings program.

- (a) ACO participants must do all of the following:

- (1) Notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program.

- (2) Post signs in their facilities to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program.

- (3) Make available standardized written notices regarding participation in an ACO and, if applicable, data opt-out. Such written notices must be provided by the ACO participants in settings in which beneficiaries receive primary care services.